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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,425	02/19/2002	Harold G. Brown	2059-0103P	1812
2292	7590	11/13/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

4c

<b>Office Action Summary</b>	<b>Application No.</b> 09/890,425	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Francisco C Prats	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-69 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____.   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

Claims 1-69 are presented for examination

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, 28, 29, 36-41, 46, 50, 51, 53-55, 57-59 and 66, drawn to a pharmaceutical composition comprising a saccharide, which may be an oligosaccharide, a sialylated oligosaccharide, a polysaccharide or a glycosaminoglycan, and an essential oil.

Group II, claim(s) 19, 36-38, 42, 43, 47, 49, 60, 66 and 68, drawn to a pharmaceutical composition comprising a glycosaminoglycan and an essential oil hyaluronic acid.

Group III, claim(s) 20-22, 48, 56 and 69, drawn to a pharmaceutical composition comprising hyaluronic acid and an essential oil.

Group IV, claim(s) 23, drawn to a pharmaceutical composition comprising a saccharide, wherein the composition does not contain an essential oil.

Group V, claim(s) 24-27, 32, 33, 35 and 52, drawn to a method of treating inflammation.

Group VI, claim(s) 30, drawn to a method of inhibiting the adhesion cascade.

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Group VII, claim(s) 31-33, drawn to a method for inhibiting tumor formation and metastasis.

Group VIII, claim(s) 33, 34 and 52, drawn to a method for treating pain.

Group IX, claim(s) 33-35, drawn to a method for treating allergy-related diseases and conditions.

Group X, claim(s) 43, drawn to a composition comprising a mannan and an essential oil.

Group XI, claim(s) 44 and 45, drawn to a method of treating pain and inflammation by administering a composition comprising a glycosaminoglycan and an essential oil.

Group XII, claim(s) 44 and 45, drawn to a method of treating pain and inflammation by administering a composition comprising a mannan and an essential oil.

Group XIII, claim(s) 61, drawn to a method of treating pruritis.

Group XIV, claim(s) 62-65 and 67, drawn to a method of preventing and treating diseases associated with adhesion, metastatic or coronary cascades, or related to allergies.

The inventions listed as Groups I through XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of JP 63-8309 and JP 59-163307 discloses compositions comprising cyclodextrin, an oligosaccharide, and an essential oil. See attached English language abstracts. Thus, the references anticipate applicant's broadest claims, including claim 1. However, neither patent mentions anything about glycosaminoglycans, or the multitude of claimed diseases suitable for treatment in applicant's method claims. Thus, each of JP '309 and JP '307 demonstrate that, as presented, the claims lack a single common technical feature which defines them over the prior art.

Moreover, the various product claims recite entirely different ingredients. For example, one set of claims recites

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the combination of a mannan and an essential oil, whereas another set of claims recites a combination of hyaluronic acid and an essential oil. Thus, because the product claims do not have the same ingredients, they clearly lack a single common technical feature. A holding of lack of unity is clearly proper.

Further still, the various process claims recite a multitude of disease conditions which have different patients. Again, these are all different diseases, and therefore lack a single common technical feature which defines them over the prior art.

In sum, in view of the demonstration by JP '309 and JP '307 that there is no single common feature present in the claims which defines them over the prior art, combined with the presented claims' recitation of a series of different products having different ingredients and the presented claims' recitation of a multitude of diseases allegedly treatable by the variety of claimed products, it is clear that a holding of lack of unity is required.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- (a) the various carbohydrates recited in the claims;
- (b) the various diseases treatable by the method claims.

In addition to electing **one** of the groups listed above, applicant is **also** required, in reply to this action, to elect a **single species**, of **each** of (a) and (b) above, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As discussed above, JP '309 and JP '307 that there is no single common feature present in the claims which defines them over the prior art. Note specifically that the oligosaccharide disclosed in the cited patents does not anticipate nor render obvious any of the other saccharides, e.g. glycosaminoglycans, recited in the claims.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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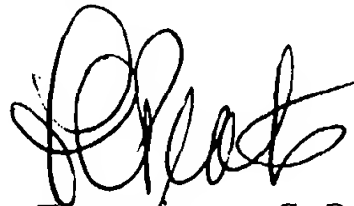
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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP